REMARKS

Office action finality

Withdrawal of the finality of the Office action dated December 2, 2004 is respectfully requested. Applicants added new claims 35-42 in the Response filed August 24, 2004. However, they were not included in any of the rejections of the pending claims on Pages 2-10 of the Office action, nor were they specifically addressed. According to M.P.E.P. 706.07, "(b) In making such final rejection, the examiner shall repeat or state all grounds of rejection then considered applicable to the claims in the application, clearly stating the reasons in support thereof." A ground of rejection was not stated for claims 35-42. Consequently, the final office was premature, and its finality should be withdrawn. M.P.E.P. 706.07(d).

11. Corrected Drawing

Corrected drawings are attached.

13. Obvious-type double-patenting

A double-patenting rejection over Application No. 10/476,614 (Attorney Docket No. IDB-0020) is not appropriate since claimed subject matter has not been indicated as allowable in either application. However, Applicant will monitor the status of both applications for conflicting subject matter.

14. Rejection under §112, first paragraph

The claims stand rejected under §112, first paragraph. Pages 4-7 of the Office action appear to be a repetition of points already made in the previous Office action. Applicant had responded to this rejection in their previous Response, as well as by adding certain new claims. However, as pointed out above, these claims were not addressed in the Final Office action.

After summarizing several points of Applicant's arguments (Applicant does not comment on the examiner's characterization of their arguments nor does Applicant necessarily embrace them as being accurate), the examiner stated on Page 8 of the Office action:

> It is the Examiner's position that the specification is not enabled for variant polypeptide sequences or fragments of 10 amino acids in length. It is not clear from the specification what epitopes if any the Applicants have specified. The location of protective epitopes has not been identified. Applicants refer to figure 3 has been noted. Figure 3 compares amino acid sequences different strains of S. *pyogenes*, in contrast *the* instant rejections is targeted toward claimed fragments. The claimed fragments encompasses 10-mer fragments, which can have 5-30% variation from the defined sequences. The fragments could be drawn from the part of the sequence which is completely different from that disclosed in the sequence identifiers. A three amino-acid variation in a 10-mer sequence is quite large and it is unclear what fragments are encompassed by this definition.

The examiner has not satisfied her burden of establishing a reasonable basis to question the enablement of the claimed invention. See, e.g., M.P.E.P. §2164.04, "Burden on the Examiner Under the Enablement Requirement."

First, no scientific basis is provided for why the information provided in the specification, and discussed in the previous Response filed on August 25, 2004, was not adequate to enable variants or fragments as alleged. A general discussion is provided on Pages 5-6 of the Office action regarding the effect of amino acid substitutions on protein activity, however, this information was already presented to Applicant in the Office action dated May 27, 2004, and Applicant responded to it the Response filed August 25, 2004. In fact, the discussion repeated in the two Office actions is largely irrelevant to the claimed subject matter since, e.g., it addresses activities such as "catalysis" (Page 5) and ligand binding of a growth factor and its subsequent ability to stimulate mitosis (e.g., Page 6). These generalities are insufficient to sustain the rejection, especially since it has not been explained how they apply to the subject matter of the claimed invention, and the specific facts disclosed in the specification. On the other hand, Claim 17 and others specifically recite "capable of generating antibodies," "wherein said polypeptide

elicits antibodies specific for BVH-P7," "at least one epitope that elicits antibodies specific for S. pyogenes," or lack an express functional limitation.

Secondly, the examiner focuses on fragments having allegedly 5-30% variation, but ignores, and does not address why the information in the specification (e.g., Pages 9-10 and Fig. 3) is not adequate to enable: (1) full-length sequences (e.g., Claim 40); (2) substantially full-length sequences plus sequence identity (e.g., Claim 39); and (3) fragments of SEQ ID NO:2 (e.g., Claims 38). Therefore, the examiner has not responded fully to Applicant's response. This was especially confusing since the latter new claims were not expressly included in any of the Rejections set forth in the Office action, nor were any deficiencies in them identified.

The statement in the Office action (see above) that "protective epitopes" have not been identified is not understood. The specification provides adequate guidance on how to identify fragments which possess such activity without undue experimentation. For example, the specification identifies sequences (e.g., Fig. 3), shows how to clone DNA segments that code for polypeptides (e.g., Example 1), including a fragment (e.g., SEQ ID NO:1) without its leader sequence (Example 2 on Page 28), and how to use DNA (e.g., Example 3) or a polypeptide (e.g., Example 5) to elicit and measure an immune response (e.g., using a chimeric polypeptide comprising a His-tag) to BVH-P7.

The information provided in the specification is adequate to meet the statutory requirements of §112, first paragraph. This was already discussed in the Response filed August 25, 2004. For example, BVH-P7 was compared for seven different strains in Fig. 3, and these shared over 95% sequence identity over their lengths. This comparison reveals variable positions where amino acid substitutions can be made. See, also Specification, Pages 9-10 for discussion of conservative amino acid substitutions. Thus, Applicants have at least seven different representative examples of BVH-P7. According to MPEP 2164.02: "For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the

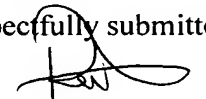
information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation." The examiner has not addressed the sufficiency of this specific information, and has not provided any adequate specific reason to doubt that the full scope of the claimed invention could be carried out without undue experimentation.

In addition to Claim 40, Claims 43-45 have been added which provide polypeptides that have sequence identity along their entire length to the complete polypeptide of the amino acid sequence set forth in SEQ ID NO: 2.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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